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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an Epidermal Growth Factor Receptor Variant III (EGFRvIII) Antibody-Drug Conjugate (ADC) for the Treatment of EGFRvIII-Expressing Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice ADC Therapeutics Ltd (ADCT), located in Lausanne, Switzerland.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Abritee Dhal, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-6154; E-mail: abritee.dhal@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 62/869,956 entitled "Monoclonal Antibodies that Bind EGFRvIII and Their Use" [HHS Ref. E-103-2019-0-US-01], PCT Patent Application PCT/US2020/040544 entitled "Monoclonal Antibodies that Bind EGFRvIII

and Their Use" [HHS Ref. E-103-2019-0-PCT-02], and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to:

The use, development, manufacturing and commercialization of an antibody-drug conjugate (ADC) having:

(1) The CDR sequences of the 40H3 monoclonal antibody

(2) a DNA-damaging or immunostimulant payload including, but not limited to, pyrrolobenzodiazepines, camptothecins, ecteinascidins, TLR/STING agonists,

for the treatment of EGFR-overexpressing tumors including, but not limited to glioblastoma, head and neck cancer, non-small cell lung cancer (NSCLC) and colorectal cancer. The license field of use excludes any (a) non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, ADCs with payloads that are not DNA-damaging, and (b) unconjugated antibodies."

Epidermal growth factor receptor (EGFR) is a transmembrane receptor for members of the epidermal growth factor (EGF) family of extracellular protein ligands. There is substantial evidence that aberrant EGFR activity is involved in the pathogenesis and progression of various types of cancers including glioblastoma multiforme (GBM). Aberrant EGFR activity is frequently associated with genetic alterations in EGFR expression (such as gene amplification) or activity (such as activating mutations). A

particularly prominent activating mutation is caused by the loss of exons 2-7 to produce EGFR variant III (EGFRvIII). This constitutively active variant of EGFR is expressed in cancer cells only. Currently, there for no effective therapy for patients with GBM. The EGFRvIII ADC can potentially be used for the treatment of GBM and other EGFR expressing cancers such as head and neck cancer, NSCLC and colorectal cancer, the ADCs can lead to the selective destruction of the cancerous cells. The development of a new therapeutic targeting EGFR will benefit public health by providing an effective treatment for patients with GBM and other solid tumors.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: August 16, 2021.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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